PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	10/694,376	Confirmation No. 5779
Applicant	:	Allen J. Brenneman	
Filed	:	October 27, 2003	
Title	:	OPTICAL REAGENT FORMAT FOR SMALL SAMPLE VOLUMES	
TC/A.U.	:	1797	
Examiner	:	Neil N. Turk	
Docket No.	:	MSE-2650	

DECLARATION OF PAUL M. RIPLEY
UNDER 37 C.F.R. § 1.132

Mail Stop RCE - via EFS
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313

Dear Commissioner:

I, Paul M. Ripley, declare that:

1. I hold the degree of B.S. in Applied Physics and Electronics from the University of Lancaster in Lancashire County in England that was obtained in 1989. I hold a M.S. in Opto-Electronics and Laser Devices and a PhD in Lasers and Optical Engineering from Heriot-Watt University located in Edinburgh, Scotland. These degrees were obtained in 1990 and 1995, respectively.

2. I have worked in a variety of optical applications over the years. For example, between 1999-2002, I worked for Los Alamos National Laboratory in Los Alamos, New Mexico researching diseases using optical techniques. From 2002 until the present, I have worked for Bayer HealthCare LLC, which is the assignee of the present invention. I have worked in researching and designing optical and electro-optical devices for patient care.

3. I have reviewed the present application entitled "Optical Reagent Format for Small Sample Volumes." I have also reviewed European Patent Application No. 0 254 246 A2 to Meserol and U.S. Patent No. 5,525,518 to Lundsgaard, which was discussed in the Office Action dated May 18, 2009.

4. The present invention is directed to a format including an input light guide coupled with an input reflector and an output light guide coupled with an output reflector. As shown in FIGS. 1-4 of the present invention, a lancet is in communication with a sample cavity disposed between the input and output reflectors. Light is guided along an optical communication path from a light input, through the input light guide, directly to the input reflector, across the sample cavity, to the output reflector, directly to the output light guide, and out of the format. The light is guided along the entire path via total internal reflection. The light is contained within a physical component of the format except when the light is directed across the sample cavity. Such a configuration guides the light with minimal light loss due to scattering.

5. Meserol is directed to a cuvette 10 used in determining a concentration of glucose or other analyte of interest in a blood sample. Column 5, lines 8-21. Specifically, Meserol is directed to a cuvette 10 having a closed wall 18 in which a beam of light 30 passes through the wall 18. See, e.g., FIGs. 2, 4-6 of Meserol. The closed wall 18 is a molded sheet of material that forms the cavity 22 of the cuvette 10. The beam of light 30 in Meserol is not guided as with the wall structure of the present invention. Rather, Meserol's cuvette is designed with many medium transitions along the light path, which result in scattered light that is subsequently lost. Specifically, Meserol discloses eight medium transitions where light can be scattered and lost. See, e.g., FIG. 5. When a sufficient amount of light is scattered and subsequently lost, it is difficult, if not impossible, to obtain an accurate analyte reading. Here, the Meserol device because of the lack of a well defined path that does not support directional wave guiding will give rise to considerable stray reflections resulting in less accurate analyte readings.

6. In summary, Meserol does not disclose, teach, or suggest (1) a light guide for guiding light from a light input to an input reflector and an output light guide for guiding light from an output reflector to a light output and (2) direct connections between light guides and reflectors to minimize light loss due to scattering.

7. Lundsgaard is directed to a method of photometric in vitro determination of blood gas parameters. Lundsgaard, Abstract. Several examples of different blood gas parameters are given in the specification including a pH of the blood, carbon dioxide content, oxygen content and hemoglobin content, and oxygen saturation. Col. 8, lines 8-42 of Lundsgaard. Meserol, on the other hand, is directed to a cuvette used in determining a glucose concentration or other analyte of interest in a liquid blood sample. Column 5, lines 8-21 of Meserol.

8. Additionally, Lundsgaard discloses a needle 20 with a traditional plunger syringe that is typically used for large blood sampling in order to see the gases. See Lundsgaard, column 7, line 61 – column 8, line 2. However, the Meserol's cuvette 10 is not of the type normally used for taking large quantities of blood. Rather, the opposite is true. Typically, only a small amount of blood sample is required to determine a glucose concentration or other analyte of interest.

9. Thus, one skilled in the art of would not look to combine Meserol, which is directed to determining analyte concentrations in small blood samples, with Lundsgaard, which is directed to in vitro determination of blood gas parameters using larger blood sampling.

10. I hereby declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true; and, further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: August 18, 2009

P.M. Ripley

Paul M. Ripley